Method for Neutralizing or Recycling Carrier Materials for Film-Like Coatings

Background of the Invention

It is well known in the art to manufacture and use sheet-like, wafer-like or film-like forms of administration of drugs, confectionary, other food, cosmetics and the like for oral application or intake; e.g. US 5,629,003, US 5,948,430, US 4,925,670 and the references cited in these patent specifications. The main advantage in using the above forms of administration, especially as regards oral intake of drugs or cosmetic active ingredients, is the avoidance of unnecessary inactive ingredients which may be contained in a tablet or capsule in an amount of up to 99 % relative to the tablet weight.

Various production processes are known for the manufacture of sheet-like, wafer-like or film-like forms of administration. For example, it is stated in US 4,925,670 that the application of the active agent-containing coating, which in many cases is an aqueous coating composition, to the carrier material preferably takes place with the aid of a smooth roll coating process. Depending on its chemical nature the coating substance may be heated e.g. to approximately 40 to 100 °C and it is applied in a thin coating using a closed application system on a roller. With delayed synchronism in specific selectable ratios the material can be transferred to a parallel roller whereby, if necessary, a reduction of the coating thickness can take place, so that simultaneously the tolerances during application are reduced by these factors.

The coating of the carrier material takes place synchronously by means of a further roller system. On adapting the active agent coating material to the release value of the carrier material, there may be no need to add an adhesive. However, optionally suitable adhesives can be added.

When applying several coating layers, the layers are successively applied with each coating optionally directed to a drying station. This can, for example, comprise a thermostatically controlled pair of rollers and a drying tunnel controllable in sectional form. After the drying process, which can take place in different separate steps at

different pre-defined temperatures, the coated material, i.e. carrier material carrying the optionally various layers of coatings, is wound on to reels.

In general, it can be said that the above mentioned sheet-like, wafer-like or film-like forms of administration are manufactured by producing thin sheets of an active-ingredient film which are applied to a carrier or substrate material by casting the film material onto the substrate material or coating a substrate material with the active agent-containing coating and winding the product on to reels. Usually in an additional step the active-ingredient containing coating is peeled off the carrier material and cut into pieces of a shape and size suitable for the intended use and the carrier material is again wound on to reels.

All these different process steps are usually carried out in a fully automated and integrated production or coating line comprising i.a. reels or roller systems, means for applying the coating to the carrier material (coating-head), e.g. a knife-over-roll coating head, and a drying tunnel with zones of different temperatures. Such coating lines are known in the art (e.g. EP-A-0 219 762).

Various materials can be used as the carrier, e.g. papers weighing approximately 80 to 120 g/m^2, plastic film or sheets comprising polyethylene, polyvinylchloride, polyvinyliden-chloride, polyesters or other polymers or thin metal foils, for example, those made from aluminum. Usually preference is given to siliconized papers which are commercially available and which have largely replaced wax or paraffin-coated release papers. Furthermore, also composite materials composed of paper, polymers and/or thin metal foils, preferably aluminum, are also advantageously used in producing the a.m. forms of administration.

As outlined above for producing these forms of administration the carrier material which is wound on to reels is fed to the production line where it is coated with the active ingredient containing material. The resulting product is dried in a drying tunnel and wound on to reels. The active-ingredient containing coating is peeled off the carrier for further processing the resulting film and the carrier material is again wound on to reels.

However, during the above production process the active-ingredient and additionally used adjuvants and other components of the coating used e.g in a pharmaceutical preparation will partly, through diffusion, penetrate into the carrier material. The carrier material will be contaminated by these substances up to the respective degrees of saturation. The same holds true with regard to cosmetically active agents and their respective components which may include e.g. breath freshening compounds like menthol other flavors or fragrances commonly used for oral hygiene.

Therefore, when applying the coating composition to the carrier material the above penetration of substances and the contamination of the carrier material has to be considered in order to arrive at a final active ingredient containing film which has the desired pre-determined composition resulting in the desired properties. This is especially important when it comes to sheet-like, wafer-like or film-like forms of administration for drugs.

Thus, once the active ingredient containing film has been peeled off the carrier material for further processing the contaminated carrier wound on to reels cannot be used again for coating purposes since it is already loaded to a non-specified degree with the substances as described above. If the carrier would be coated with the same coating material a second time the active ingredients, adjuvants, flavors etc. would to a different extent penetrate into the pre-loaded carrier as compared to the first coating procedure and, thus, the composition of the resulting active ingredient containing coating or film could change significantly. Especially this is not tolerable as regards film-like administration forms of drugs.

The same problem arises if one would apply to the pre-loaded carrier material a coating of different composition. Additionally this coating could be contaminated by substances penetrating from the pre-loaded carrier into the new coating.

Therefore, usually any further use of such carrier material is almost not possible. Since the costs for carrier materials contribute largely to the overall production costs, and also from an environmental perspective in terms of removing of waste, it would be highly

desirable to neutralize, recycle or recondition these carrier materials for further use.

Summary of the Invention

The present invention provides a method for neutralizing, recycling or reconditioning of carrier materials used in the manufacture of sheet-like or film-like forms of administration of drugs, confectionary, other food, cosmetics and the like for further use.

Detailed Description of the Invention

The present invention provides a method for removing substances, e.g. active ingredients, adjuvants, flavors etc., from carrier materials which have penetrated these carrier materials while producing the above mentioned forms of administration.
As stated above the contaminated carrier materials are usually wound on to reels once the film coating as been peeled off. It has been found that by an appropriate thermal treatment of these carrier materials the contaminants, i.e. the substances which penetrated the material during the production process, can be removed there from resulting in a so-called neutralized carrier material being essentially free of those contaminants, which then can be used as carriers in further coating processes.

The period of the thermal follow-up treatment and the temperatures to be applied vary depending mainly from the following features:

1. concentration of the contaminating substances in the carrier material (degree of contamination)

2. type of substances (chemical and physical characteristics) and type of coating compositions (usually aqueous compositions)

3. type of carrier material (e.g. paper, polymers, composite materials from paper, polymers and/or thin metal foils)

However, time and temperature can be easily assessed through simple experiments using conventional means and methods of chemical analysis.

In most cases good results in removing the contaminating substances from conventional carrier materials are achieved by treating these materials at approx. 80° C for a period of approx. 0.5 to 6 minutes.

This process can for example be performed in an automated manner by unwinding the contaminated carrier from a reel and feeding it to a thermal treatment zone, like the drying tunnel of a coating line, where the material is heated, e.g. by infra red heating, to the appropriate temperature. The time of treatment can be controlled via the speed at which the material is passing the thermal treatment zone. The contaminating substances will evaporate and can be feed to a thermal after-burning using a controlled air circulation. Having passed this heating zone the carrier material, if necessary, can be cooled down by using a material compensator and is then feed again to the coating-head of a coating line for the next coating step. Thus, the removal of the undesired substances contaminating the carrier material can be carried out by using a slightly modified conventional coating line.